

Performance in Initiating Clinical Research

1 January 2016 - 31 December 2016

Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?	Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	Comments	Reasons for delay correspond to:
09/H1008/137	24269	The long-term Safety and Efficacy of Biologic Therapies in Children with Rheumatic Diseases (BSRBR-JIA)	12/01/2016	13/01/2016	Yes	21/03/2016	1	68	69	Yes		Unknown
13/EM/0459	137785	POSNOC - POSitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early stage breast cancer who have metastases in one or two sentinel nodes.	13/01/2016	13/01/2016	Yes	21/03/2016	0	68	68	Yes		Unknown
15/NI/0207	187243	Toolkit to benchmark young person friendly services in rheumatology	26/02/2016	08/03/2016	Yes	14/03/2016	11	6	17	Yes		Unknown
14/YH/1259	163195	Comparison of Alitretinoin with PUVA as the first line treatment in patients with severe chronic hand eczema (ALPHA)	21/03/2016	22/03/2016	Yes	15/08/2016	1	146	147	No	Sponsor has insisted on processing an amendment before recruitment could commence	Sponsor
15/EM/0492	189756	A retrospective real world research study to describe the use of buccal midazolam maleate (Epistatus <sup>®</sup> ) in adults in routine practice in the UK	18/01/2016	18/01/2016	Yes	02/02/2016	0	15	15	Yes		Unknown
15/WA/0241	183747	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus - Study Two	22/03/2016	22/03/2016	Yes	09/05/2016	0	48	48	Yes		Unknown
15/EE/0464	183877	CRIT 4440 - A Phase 3, Placebo-Controlled, Randomized, Double-Blind, Multi-Center Study of LJPC-501 in Patients with Catecholamine-Resistant Hypotension (CRH)	25/04/2016	27/04/2016	Yes	23/06/2016	2	57	59	Yes		Unknown
13/SC/0645	143871	Pre-eclampsia in Hospital: Early Induction or Expectant Management	02/04/2016	02/04/2016	Yes	10/06/2016	0	69	69	Yes		Unknown
16/SW/0130	203567	StartRight: Getting the right classification and treatment from diagnosis in young adults with diabetes	14/09/2016	15/09/2016	Yes	07/11/2016	1	53	54	Yes		Unknown
14/SW/1166	164941	INFORM - A multicentred randomised trial to compare 1stage with 2stage revision surgery for prosthetic hip joint infection	13/06/2016	02/08/2016	No		50			No	Delay as awaiting evidence of rec approval for trial documentation	Sponsor

16/EM/0133	184873	A randomised, double-blind, placebo-controlled multicentre study of secukinumab to evaluate the safety, tolerability and efficacy up to 2 years in patients with active nonradiographic axial spondyloarthritis	12/07/2016	11/08/2016	Yes	20/12/2016	30	131	161	No	Site initiated 14/10/2016	Sponsor
16/EE/0053	172067	AddIT Follow Up - Tracking of risk for diabetic nephropathy and cardiovascular disease in young people with Type 1 diabetes recruited to the AdDIT study	06/09/2016	07/09/2016	Yes	24/10/2016	1	47	48	Yes		Unknown
14/EM/1295	163111	Affinitie: Two cluster RCTs to evaluate feedback in blood transfusion audits	09/05/2016	21/06/2016	Yes	14/07/2016	43	23	66	Yes		Unknown
15/LO/2202	190754	BOSS - The British Orthopaedic Surgery Surveillance Study: A nationwide service evaluation, and nested-cohort study.	27/04/2016	18/08/2016	Yes	21/10/2016	113	64	177	No	Permissions denied pending further clarification regarding use of ionising radiation	Sponsor
16/NE/0027	187317	Javelin - A phase 3, multicenter, randomized, open-label study of avelumab (msb0010718c) alone or in combination with pegylated liposomal doxorubicin versus pegylated liposomal doxorubicin alone in patients with platinum-resistant/refractory ovarian cancer	19/10/2016	07/11/2016	Yes	10/11/2016	19	3	22	Yes		Unknown
15/LO/0545	172357	CARAT - Clinical and device functional assessment of real world ICD patients	28/10/2016	02/12/2016	No		35			Within 70 Days		Unknown
15/EC08/0008	160678	MEMORYCARE - Investigating the management of refusal of care: people with Dementia	20/12/2016	21/12/2016	Yes	09/01/2017	1	19	20	Yes		Unknown
16/WA/0034	187658	PAIPMS - Psychological adjustment in people with progressive multiple sclerosis. A longitudinal study	27/10/2016	06/12/2016	No		40			Within 70 Days		Unknown
14/SC/1150	158370	REDDS - Red blood cell transfusion thresholds and Quality of Life in myelodysplastic syndromes: a pilot, feasibility study	10/11/2016	08/12/2016	No		28			Within 70 Days		Unknown